July 29, 2022

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K150200
Trade/Device Name: CD HORIZON® Growth Rod Conversion Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Mr. Grant:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 25, 2015. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

February 25, 2015

Re: K150200
Trade/Device Name: CD HORIZON® Growth Rod Conversion Set
Regulatory Class: Unclassified
Product Code: PGM
Dated: January 20, 2015
Received: January 29, 2015

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K150200

Device Name
CD HORIZON® Growth Rod Conversion Set

Indications for Use *(Describe)*

The CD HORIZON® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency including early-onset scoliosis. The CD HORIZON® Growth Rod Conversion Set may be used with any cleared traditional CD HORIZON® Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK rods, SPIRE™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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**CD HORIZON® Growth Rod Conversion Set**
**510(k) Summary – K150200**
**February 2015**

**I. Submitter:**

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901)396-3133
Fax: (901) 346-9738

**Contact:** Lee Grant
Distinguished Regulatory Affairs Advisor

**Date Prepared:** January 16, 2015

**II. Device**

**Name of Device:** CD HORIZON® Growth Rod Conversion Set

**Common Name:** Spinal Fixation Appliance

**Classification Name:** Growing Rod System

**Regulatory Class:** Unclassified

**Product Codes:** PGM

**III. Predicate Device** K133904 (SE 2/25/2014) CD HORIZON® Growth Rod Conversion Set – Primary Predicate

*The predicate device has not been subject to a design related recall.*

**IV. Device Description:**

The CD HORIZON® Growth Rod Conversion Set consists of a variety of connectors designed to convert a traditional fusion construct into a non-fusion growth enabling construct which can be surgically lengthened on a periodic basis as the patient grows. The CD HORIZON® Growth Rod Conversion Set components are manufactured from stainless steel or titanium alloy and are designed to interact with rod-based pedicle screw/hook constructs in which the rods range in diameter from 3.5mm to 5.5mm. The CD HORIZON® Growth Rod Conversion Set is specifically to be used with any traditional CD HORIZON® Spinal System (3.5mm to 5.5mm) fusion construct cleared for pediatric usage. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK Rods, SPIRE® Spinous Process Plates and/or Shape Memory Alloy (SMA) Staples. The CD HORIZON® Growth Rod Conversion Set is limited to a posterior approach. The CD HORIZON® Growth Rod Conversion Set connectors are provided in both sterile and non-sterile form. The sterile implants are sterilized via gamma irradiation.

The purpose of this 510(k) submission is to add sterile connectors and set screws to the CD HORIZON® Growth Rod Conversion Set utilizing gamma irradiation and sterile packaging. The subject components are manufactured out of medical grade titanium alloy per ASTM F136 or medical grade stainless steel per ASTM F138.

## V. Indications for Use:

The CD HORIZON® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The CD HORIZON® Growth Rod Conversion Set may be used with any cleared traditional CD HORIZON® Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK Rods, SPIRE™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples.

## VI. Comparison of Technological Characteristics with Predicate Device

The subject CD HORIZON® Growth Rod Conversion Set implants have the same fundamental scientific technology as the predicate CD HORIZON® Growth Rod Conversion Set implants for the treatment of an identical patient population for the same indications of use. All of the implants included in this application were previously cleared in K133904 (SE 02/25/14), the only differences being that the subject implants will now be offered as pre-packaged sterile implants and the connectors will come with pre-loaded set screws. The subject connectors and set screws are identical in design, materials used to manufacture the implants, size, method of implantation and intended use. As stated previously the subject implants will be provided to the end user in a sterile state with sterilization performed via gamma irradiation.

## VII. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

**Biocompatibility**

The subject CD HORIZON® Growth Rod Conversion Set implants are permanent implants and are manufactured from stainless steel in accordance with ASTM F138 Standard Specification for Wrought 18Chromium-14Nickel- 2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants, or from titanium alloy in accordance with ASTM F136: Standard Specification for Wrought Ti-6Al-4V ELI Alloy for Surgical Implants. These materials are identical to the

materials used to manufacture the predicate CD HORIZON® Growth Rod Conversion Set implants cleared in K133904. According to the aforementioned standards, all of the materials used to manufacture the subject devices have a well characterized level of local biological response and a long history of clinical use in medical devices; therefore, no additional biocompatibility testing is required.

**Mechanical Testing**

No mechanical testing was performed on the subject connectors and set screws as no design changes were made to the implants. In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to predicate device. It was determined that subject devices do not represent a new worst case. Packaging and sterilization assessment/rationales were used to demonstrate substantial equivalence in accordance with the following standards:

ANSI/AAMI/ISO 11137-1:2006/ A1:2013, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
ANSI/AAMI/ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing a sterilization dose.
ASTM F88/F88M-09: 2009 Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D4169-09 – 2009: Standard Practice for Performance Testing of Shipping Containers and Systems (Sterility).
ASTM F1929-98: 2004 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

As a new worst case has not been indicated, the sterilization and packaging rationales were deemed adequate to prove equivalence to the predicate device and no additional mechanical testing is required.

## VIII. Conclusion

Based on a risk analysis, packaging and sterilization rationales, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Growth Rod Conversion Set components are substantially equivalent to the predicate devices found in K133904 (SE 02/25/14).